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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,958	07/24/2001	Brian S. Hooker	059440-0138	3645

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,958

Applicant(s)

HOOKE ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/30/2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/14/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

RCE Acknowledgment

1. The request filed on October 1, 2003 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/910958 is acceptable and a RCE has been established. An action on the RCE follows.

2. Claims 70-84 are pending and are examined in the present office action.

Claims 1-69 have been canceled.

Drawings

3. Figures 3, 6B, 9, 11 and 12 are objected to because no discernable information can be obtained. The images only show black. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 70-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

In claim 70, the metes and bounds of "environmental factor" have not been defined. It is unclear to what factors Applicant is referring. All subsequent recitations of "environmental factor" are also rejected.

In claim 70, line 8, replace " the cultivating" with --cultivation-- to correct the grammar.

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In claim 70, line 10, replace the second "the" with --said-- to better clarify Applicants' invention.

In claim 70, line 11, replace the first "the" with --said-- to better clarify Applicants' invention.

In claim 70, line 12, replace the first and second "the" with --said-- to better clarify Applicants' invention.

In claim 71, line 1, insert --an amount at-- after the word "at", to correct the grammar.

In claim 71, line 2, insert --produced-- after the word "be" to better clarify Applicants' invention.

In claim 77, line 1, replace the second "the" with --said-- to better clarify Applicants' invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 70-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al (January, 1999, U.S. Patent 5,861,277) and further in view of Fladung et al (1993 Plant

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Molecular Biology 23:749-757 listed in IDS) taken with Goodman et al (September, 1990, U.S. Patent Number 4,956,282).

The claims are drawn to a method of producing a protein of interest comprising transforming a plant with nucleic acid material comprising a coding sequence operably linked to a light inducible promoter, wherein the transformed plant is grown in an environment wherein the source of light is controllable and induces expression of said coding region, followed by harvesting the expressed protein. Applicants' claims are also drawn to said method wherein said protein is produced at a concentration at least two fold greater than what would be achieved growing said plants in a field. Applicants' claims are further limited wherein the amount of light is at least 18 hours, 20 hours or 24 hour a day, and wherein the plant is either a *Solanum*, *Spinacia* or *Brassica* species, and wherein the light-inducible promoter is from the Rubisco small subunit gene, and wherein the transgenic potato plant produces between 0.2 kg and 5.0 kg of fresh weight vines per plant.

Rose et al teach transforming a plant (columns 19-21), wherein the plant is a potato plant (column 6, line 42) with a heterologous nucleic acid encoding a protein (column 6, lines 11-67) and growing said transgenic plant under defined conditions (column 21, lines 25-41). Rose et al also disclose extracting proteins to verify expression levels of the heterologous proteins (column 9, figure 4. and column 28-29, Example 9), and wherein the plant is also a Brassica plant (column 6, lines 37-42).

Rose et al do not teach a light-inducible promoter or a light-inducible promoter from the small subunit of Rubisco, a greater production of said protein said plant is grown under

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controlled conditions compared to growing said plant in the field, using 18, 20 or 24 hours of light a day, and producing between 0.2 kg and 5.0 kg of fresh potato vine weight per plant.

Fladung et al teach the light-induced Rubisco small subunit promoter and its use to regulate heterologous gene expression in transformed potato (page 750, right column, 1st paragraph).

Goodman et al teach a system for expressing a peptide in plant cells for the purpose of harvesting the peptide from the transformed plant material and include in their disclosure the light inducible ribulose-1,5-bisphosphate promoter (paragraph bridging column 1 and 2, and column 2, lines 54-57).

Given the recognition of those of ordinary skill in the art of the value of producing a protein in a transformed plant that is grown in a controlled environment as taught by Rose et al, and given the disclosure of Goodman et al that teach a system for expressing a polypeptide that is to be harvested from a plant and using a light inducible ribulose-1,5-bisphosphate promoter, and given the disclosure of Fladung et al that teach the light-induced Rubisco small subunit promoter, it would have been obvious to design a method for the production of a polypeptide of interest comprising transforming a plant with a construct comprising a nucleic acid encoding a polypeptide of interest transformed into a plant that is grown in a controlled environment as taught by Rose et al and to incorporate the light-induced Rubisco small subunit promoter operably linked to the nucleic acid as taught by Fladung et al in light of the Goodman et al disclosure. No patentable weight is given to claims drawn to 18, 20 or 24 hours of light per day as this range would be covered under optimization of process parameters, as well as claim 71 drawn to a two fold greater concentration of protein produced in a controlled environment

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compared to the field, as well as the limitation that between 0.2 kg and 5.0 kg of fresh weight vine per plant is harvested according to the method of claim 81, and lastly, the choice of one plant over another, i.e., *Spinacia* over *Brassica* is merely a design choice and holds no patentable weight one over the other, MPEP 2144.05.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

December 19, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

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